

EXHIBIT B

** C O N F I D E N T I A L **

** OUTSIDE ATTORNEYS' EYES ONLY **

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN,)	MDL NO. 2875
)	
AND IRBESARTAN PRODUCTS)
)	
LIABILITY LITIGATION) HONORABLE ROBERT B.
)	KUGLER,
_____)	DISTRICT COURT JUDGE

** C O N F I D E N T I A L **

** OUTSIDE ATTORNEYS' EYES ONLY **

RULE 30 VIDEOTAPED DEPOSITION
PHILIP JAMES RUSS
THURSDAY, JANUARY 5, 2023

REPORTED BY: DAYNA HESTER, C.S.R. 9970

1 CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY VIDEOTAPED
2 DEPOSITION OF PHILIP JAMES RUSS, TAKEN ON BEHALF OF
3 DEFENDANTS, AT 9:20 A.M., THURSDAY, JANUARY 5, 2023, AT
4 GREENBERG TRAURIG LLP, 1840 CENTURY PARK EAST, SUITE 1900,
5 LOS ANGELES, CALIFORNIA, WITH MULTIPLE PARTICIPANTS
6 APPEARING REMOTELY, BEFORE DAYNA HESTER, C.S.R. NO. 9970,
7 PURSUANT TO NOTICE.

8

9 APPEARANCES OF COUNSEL:

10 FOR PLAINTIFF(S):

11 KANNER & WHITELEY, L.L.C.
12 BY: DAVID J. STANOCH, ESQ.
(PRESENT IN PERSON)
13 BY: CONLEE S. WHITELEY, ESQ.
(PRESENT VIA ZOOM VIDEOCONFERENCE)
701 CAMP STREET
14 NEW ORLEANS, LOUISIANA 70130
(504) 524-5777
15 D.STANOCH@KANNER-LAW.COM

16 -AND-

17 HONIK LLC
18 BY: RUBEN HONIK, ESQ.
(PRESENT VIA ZOOM VIDEOCONFERENCE)
1515 MARKET STREET, SUITE 1100
19 PHILADELPHIA, PENNSYLVANIA 19102
(267) 435-1300
20 RUBEN@HONIKLAW.COM

21 -AND-

22 MAZIE SLATER KATZ & FREEMAN, LLC
23 BY: CHRISTOPHER J. GEDDIS, ESQ.
(PRESENT VIA ZOOM VIDEOCONFERENCE)
103 EISENHOWER PARKWAY
24 ROSELAND, NEW JERSEY 07068
(973) 228-9898
25 CGEDDIS@MAZIESLATER.COM

1 audit reports if it's not necessary.

2 So would you -- during those audits of
3 ZHP, would you expect the auditor to conduct the
4 type of analysis that led Novartis to identify the
5 NDMA substance in the Valsartan API?

6 A. No.

7 Q. Turning to your -- your report which -- if
8 you have before you.

9 A. Uh-huh.

10 Q. At the top of Page 9 -- and this is a
11 quotation, I believe, from the NDA guidance.

12 But you have quoted at the bottom of that
13 quote [as read]:

14 "The finished drug product
15 manufacturer should also ensure that
16 compendial-grade APIs comply with
17 compendial specifications."

18 Do you see that?

19 A. Yeah. This is -- I do see that.

20 This is a statement from the questions and
21 answers, I believe. This is not the guidance but
22 Exhibit 10.

23 Q. Okay. So is it your understanding that
24 the -- that the Valsartan produced by Teva complied
25 with all the applicable compendial specifications?

1 MR. STANOCH: Objection.

2 THE WITNESS: The material -- there is a
3 compendial monograph for Valsartan. Teva identifies
4 their -- Valsartan as U.S. -- what is called "USP" or
5 "United States Pharmacopeia" on the labeling. It
6 would be incumbent upon them to assure compliance with
7 the compendial specifications.

8 BY MS. LOCKARD:

9 Q. And you haven't seen any evidence in the
10 documentation that Teva's product did not comply
11 with the compendial specifications; right?

12 A. No. I don't have issue with Teva's
13 compliance to compendial specifications for
14 Valsartan they received.

15 MS. LOCKARD: So let's mark this as
16 exhibit...

17 THE REPORTER: 16.

18 (Deposition Exhibit 16 was marked for
19 identification and is attached hereto.)

20 BY MS. LOCKARD:

21 Q. All right. Is this -- what is this? Do
22 you recognize this document?

23 A. [Witness reviews document].

24 Yeah. This is the USP-NF Online monograph
25 for Valsartan drug substance.

1 chromatography -- I can't find a penny that I lost
2 if I don't look for a penny that I lost.

3 Q. Okay. Well, I just want to make sure I
4 understand your opinions.

5 A. No.

6 Q. There is nothing that Teva -- there is no
7 evidence in Teva's records that there was an Out of
8 Trend report that they failed to act on; right?

9 MR. STANOCH: Objection.

10 Go ahead.

11 THE WITNESS: What is -- what my concern is,
12 is that there isn't anything in the record that shows
13 that Teva evaluated chromatography for the drug
14 substance they were receiving from ZHP.

15 BY MS. LOCKARD:

16 Q. I understand your concern being that, from
17 your review, you don't feel that Teva did an
18 adequate review of the chromatography.

19 But my question to you is, based on what
20 is in the documentation, you found nothing to
21 suggest Out of Trend results; right?

22 MR. STANOCH: Objection.

23 THE WITNESS: I didn't find an Out of Trend
24 investigation around peaks in the chromatography, no.

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